doctor. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.''

(2) ''This product may cause temporary burning and irritation on being instilled into the eye.''

(3) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.

§ 349.75 Labeling of ophthalmic vasoconstrictor drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a ''redness reliever'' or ''vasoconstrictor (redness reliever)'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., drops).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following phrase: ''Relieves redness of the eye due to minor eye irritations.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.18:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.''

(2) ''If you have glaucoma, do not use this product except under the advice and supervision of a doctor.''

(3) ''Overuse of this product may produce increased redness of the eye.''

(4) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 to 2 drops in the affected eye(s) up to four times daily.

EFFECTIVE DATE NOTE: At 65 FR 38428, June 21, 2000, § 349.75 was amended by revising paragraph (c)(2) and by adding paragraph (c)(5), effective May 16, 2002. For the convenience of the user the revised and added text is set forth as follows:

(c) * * *

(2) ''Ask a doctor before use if you have [in bold type] narrow angle glaucoma.''

* * * * *

(5) ''When using this product [in bold type] pupils may become enlarged temporarily.''

§ 349.78 Labeling of eyewash drug products.

(a) *Statement of identity.* The labeling of the product identifies the product with one or more of the following terms: ''eyewash,'' ''eye lotion,'' or ''eye irrigating solution.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' one of the following phrases:

(1) ''For'' (select one of the following: ''flushing,'' ''irrigating,'' ''cleansing,'' ''washing,'' or ''bathing'') ''the eye to remove'' (select one or more of the following: ''loose foreign material,'' ''air pollutants (smog or pollen),'' or ''chlorinated water'').

(2) ''For'' (select one of the following: ''flushing,'' ''irrigating,'' ''cleansing,'' ''washing,'' or ''bathing'') ''the eye to help relieve'' (select one or more of the following: ''irritation,'' ''discomfort,'' ''burning,'' ''stinging,'' ''smarting,'' or ''itching'') ''by removing'' (select one or more of the following: ''loose foreign material,'' ''air pollutants (smog or pollen),'' or ''chlorinated water'').

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for all eyewash products:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.''

(2) ''Obtain immediate medical treatment for all open wounds in or near the eyes.''

(3) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For eyewash products intended for use with an eyecup.* Rinse cup with

clean water immediately before each use. Avoid contamination of rim and inside surfaces of cup. Fill cup half full and apply the cup to the affected eye, pressing tightly to prevent the escape of the liquid, and tilt the head backward. Open eyelids wide and rotate eyeball to ensure thorough bathing with the wash or lotion. Rinse cup with clean water after each use.

(2) *For eyewash products intended for use with a nozzle applicator.* Flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle.

§ 349.79 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part.

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the indication(s) for each ingredient in the combination, as established in the indications sections of this part.

(c) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the warning(s) for each ingredient in the combination, as established in the warnings sections of this part.

(d) *Directions.* The labeling of the product states, under the heading ''Directions,'' directions that conform to the directions established for each ingredient in the directions sections of this part. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

§ 349.80 Professional labeling.

The labeling of any OTC ophthalmic demulcent drug product provided to health professionals (but not to the general public) may contain instructions for the use of these products in professional eye examinations (i.e. gonioscopy, electroretinography).

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

352.1 Scope.
352.3 Definitions.

Subpart B—Active Ingredients

352.10 Sunscreen active ingredients.
352.20 Permitted combinations of active ingredients.

Subpart C—Labeling

352.50 Principal display panel of all sunscreen drug products.
352.52 Labeling of sunscreen drug products.
352.60 Labeling of permitted combinations of active ingredients.

Subpart D—Testing Procedures

352.70 Standard sunscreen.
352.71 Light source (solar simulator).
352.72 General testing procedures.
352.73 Determination of SPF value.
352.76 Determination if a product is water resistant or very water resistant.
352.77 Test modifications.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 64 FR 27687, May 21, 1999, unless otherwise noted.

EFFECTIVE DATE NOTE: At 64 FR 27687, May 21, 1999, part 352 was added, effective May 21, 2001. At 65 FR 36319, June 8, 2000, the effective date was delayed through Dec. 31, 2002. At 66 FR 67485, Jan. 30, 2002, the effective date was stayed until further notice.